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| EXAMINER | |
|---|---|
| WEGERT, SANDRA L | |

| ART UNIT | PAPER NUMBER |
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| 1647 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/718,598 | MCKERRACHER, LISA | |
| | Examiner | Art Unit | |
| | Sandra Wegert | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *4 and 7-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## Detailed Action

***Status of Application, Amendments, and/or Claims***

The Information Disclosure Statement, sent 1 March 2004, has been entered into the record. Applicant elected Invention I (Claims 1-3, 5 and 6, as reading on a collagen matrix) in the response filed 5 February 2007. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 4 and 7-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-3, 5 and 6 are under examination in the current application.

***Suggestions***

Regarding claims 1-3, 5 and 6, the phrase "axon *growth*" is not indefinite, but is somewhat vague. It is suggested that the phrase "axon *growth*" be replaced by a phrase that more accurately describes the process of axonal elongation, such as, for example, "sprouting" as recited in the claims of the parent US patent 7,141,428. This modification is suggested, but not required.

## Informalities

***Figures***

Figure 9 is objected to because it is not clear from the figure or from the specification what the components of the algorithm are, and such information is crucial to an understanding of the claimed invention. More specifically, it is not clear what is contained in each square of the diagram (e.g., they are "blank"). Corrections will be required in the event there are allowable claims, however the Applicant is cautioned about adding *new matter* to the Specification.

## *Claim Rejections*

**35 *USC § 112, second paragraph, indefiniteness***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reciting or encompassing the phrase "container means." It is not clear from the Specification if this refers to a container or a means of performing a function. Since the invention as described in the Specification refers to a syringe-like apparatus, it is assumed that "container means" refers to a compartment or container. Modifying the phrase to read "compartment" or "container," for example, would be remedial.

***Non-Statutory Double-Patenting.***

**The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).**

**A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).**

**Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).**

Claims 1, 2, 5 and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 7,141,428. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active ingredients cited in each are identical; therefore, what is obvious in the Patent versus the instant Application is the matrix comprising cytoskeletal inhibitors. Evidence for this is revealed in the data of Figures 1-10 of the 7,141,428 Patent which are identical to the data put forth in Figures 1-10 of the instant Application, showing the same kit and composition in the Patent versus the instant Application.

**35 *USC § 112, first paragraph-scope of enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an axon-elongation stimulation kit comprising *C3* at tested concentrations (e.g., corresponding to a final *in situ* concentration of 25-50μg/ml), combined in a collagen gel matrix with protease inhibitors, is not enabled for an axon-growth stimulation kit comprising two or more containers containing components *capable of forming a therapeutically acceptable matrix*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-3, 5 and 6 are directed to an axon growth stimulation kit comprising a compartment or compartments for containing components capable once intermingled of forming a flowable carrier component and a second container for a therapeutically active agent for facilitating axon growth at a site of injury in vivo. The scope of the patent protection sought by the Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification for the following reasons:

The specification is not enabled for the full scope of the claimed apparatus, wherein the apparatus comprises compartments containing components "capable once intermingled of forming a flowable carrier component and a second container with a therapeutically active agent for facilitating axon growth at a site of injury" with the assurance that the apparatus claimed can be made and used without undue experimentation and with the assurance that it would have the desired properties. There are no examples of what specific compounds would be used in the apparatus or fall within the range of those that would be included and still be useful for facilitating axon growth. Furthermore, the field of neural development is not well-established in

terms of clearly defining the specific series of compounds and steps involved in causing axon elongation in vivo. For example, many classes of compounds, including cytoskeletal proteins, growth factors and growth-inhibiting factors are involved in *in vivo* guidance of each axon, at least during development (Zigmond, M.J., editor, 1999, Fundamental Neuroscience, Academic Press, pages 526-543). Still less is known about axon elongation after injury in adult animals, but since central nervous system axon growth is rarely seen after injury in adults, it can be assumed that there exist barriers to such growth.

The specification discloses enabled compounds for an axon-elongation stimulation kit comprising *C3* at tested concentrations (e.g., corresponding to a final *in situ* concentration of 25-50$\mu$g/ml), combined in a collagen gel matrix with protease inhibitors. However, the instant claims read on an apparatus with multiple compartments comprising any combination of peptide or non-peptide compounds that are mixed with any thixotrope to form a matrix for in vivo application.

Due to the large quantity of experimentation required to determine how to use the kit and composition described to stimulate axon growth, the lack of direction or guidance in the specification regarding same - e.g., the lack of guidance regarding use of components other than *C3* combined with collagen matrix, the lack of working examples to all variants of the claimed components, the state of the art showing the many types of compounds that can cause axon elongation, the unpredictability of function of most injected compounds in terms of causing axon elongation, and the breadth of the claims which embrace innumerable compounds defined only vaguely and only in terms of function- undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

***35 USC § 112, first paragraph – Written Description.***

Claims 1-3, 5 and 6 are rejected under 35 USC § 112, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 5 and 6 are directed to an axon growth stimulation kit comprising a compartment or compartments for containing components capable of forming a flowable carrier component and a second container for a therapeutically active agent for facilitating axon growth at a site of injury in vivo.

The instant specification teaches use of *C3* and collagen, as well as a protease inhibitor in the axon growth stimulation kit. However, the specification does not teach functional or structural characteristics of other compounds that may be used in the kit. The description of several compounds described only as capable of stimulating axon growth or of forming a flowable matrix is not adequate written description of an entire genus of functionally equivalent compounds that stimulate axon growth or form a flowable matrix.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the C3 and the collagen matrix compounds referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed compounds, and therefore, would not know how to make or use them. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making or using. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use. *The product itself is required.* See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only descriptive factor present in the claims is the recitation of the requirement that the components can form a therapeutically acceptable matrix in vivo. In the absence of a sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Therefore, only the kit and composition comprising *C3* and the enabled components of a collagen matrix, but not the full breadth of the claims, meets the written description provision of

35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***35 USC § 102- Prior Art***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

Claims 1 and 2 are rejected under 35 USC 102(b), as being anticipated by Redl, et al (US Patent 4,631,055 23 December 1986). Redl, et al teach a two-compartment apparatus for dispensing a composition for in vivo use. It should be kept in mind that phrases used in the claims of the instant Application, such as: "for containing a therapeutically-acceptable matrix" and "facilitating axon growth at the lesion site" are intended-use phrases and are not given patentable weight in regards to prior inventions.

The instant Claims make no mention of properties that distinguish the claimed apparatus from those disclosed in the US Patent 4,631,055 23 (Redl, 1986) such as, for example: exact compositions of injected proteins and the concentrations of the ligand proteins listed in the examples of the instant Specification (e.g., "collagen" with C3 at 25-50$\mu$g/ml).

***Conclusion***: Claims 1-3, 5 and 6 are rejected for the reasons listed above.

**Advisory information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW
22 April 2007

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER